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EXAMINER	
RAE, CHARLESWORTH E	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,278	HOSSAINY ET AL.	
	Examiner	Art Unit	
	CHARLESWORTH RAE	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11 and 13-27* is/are pending in the application.

4a) Of the above claim(s) *14-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11, 13, and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Comment [C1]:

DETAILED ACTION

Applicant's arguments/amendment, received 2/11/08, have been considered and Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114, received 4/15/08.

Status of the Claims

Claims 1-11, 13-27 are currently pending in this application.

Claims 14-26 are withdrawn for being directed to non-elected subject matter.

Claims 1-11, 13, and 27 are under examination.

Amendment

Applicant's following statements are acknowledged:

1) Claims 1, 3 and 13 have been amended; claim 12 has been canceled; claim 27 is new.

2) Support for the claim amendment can be found in the publication of the instant application: US 2005/0106204, e.g. para. 0075-0076; and 0079.

3) No new matter is introduced by the claim amendment.

Information Disclosure Statement

Applicant's request for an initialed copy of the following is acknowledged (see also applicant's Response, received 4/15/08, at pages 10-11):

1) IDS filed on March 4, 2004, as applied to references A60 (US 5,997,517) and B22 (WO 97/10011); and

2) IDS filed June 9, 2005, as applied to reference C1 (ISR and Written Opinion for PCT/US2004/038135).

Terminal Disclaimers

The grant of approvals of applicant's terminal disclaimers with respect to copending application 11/641,250, and US Patent 7,169,404, 7,214,759, and 7,186,789, are acknowledged.

Response to applicant's arguments/remarks

Claim Objection

The objection is withdrawn in view of applicant's claim amendment.

Lack of written description under 112, 1st para

This rejection is withdrawn in view of the claim amendment and applicant's persuasive arguments (see applicant's Response, received 2/11/08, at page 11).

Rejection under 112, 2nd para.

Applicant contends that this rejection is rendered moot by the claim amendment and should be withdrawn (see applicant's Response, received 4/15/08, at page 12).

In response, the rejection is withdrawn except as set discussed below in connection with the rejection under 112 2nd para.

Rejection under 102(b)

This rejection is withdrawn in view of applicant's claim amendment.

Rejection under 103(a)

This rejection is withdrawn in view of applicant's claim amendment.

ODP Rejections

The ODP rejections are withdrawn in view of the approval applicant's terminal disclaimers as indicated above.

REJECTIONS

Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11, 13, and 27 are rejected under 103(a) as being unpatentable over Smith et al. (US Patent 6,451,337), Llanos et al. (US Patent Publication No. 2002/0094440 A1; already made of record), and Hunter et al. (US Patent Application Pub. No. 2005/0147643 A1), in view of Zhu et al. (US Patent 6,331,547) and Griffiths et al. (US Patent 7,011,812).

It is noted that applicant's elected invention is directed to an implantable article comprising a coating composition comprising (see applicant's Response to the restriction/election requirements, received 4/27/07, at page 10_:

a) Solef i.e. the fluoropolymer species;

b) a poly(ester amide) polymer having the general formula recited in claim 11, wherein R is H, as the beneficial polymer species.

c) a conjugated biologically active agent, wherein said active agent is conjugated to the beneficial polymer species.

Smith et al. (US Patent 6,451,337) is added to show the general state of the art regarding polymeric coating compositions for use on implantable medical devices such as stents comprising polymeric conjugates of diazenium diolates (col. 3, lines 63 to col. 4, lines 3; col. 13, lines 62-67; and reference claims 13-14). Smith et al. (US Patent 6,451,337) disclose that there remains a great need to develop a low cost, readily biodegradable, biocompatible nitric oxide donor polymer composition comprising a nitric oxide dimer and a medically beneficial carrier molecule capable of improved site specific delivery and controlled release of nitric oxide (NO) to target tissues under physiological conditions, without the further side effects of the nitric oxide donor compounds (col. 3, lines 63 to col. 4, lines 3). Smith et al. teach a chitosan-based polymeric composition capable of site specific delivery and controlled release of nitric oxide to target tissues comprising a modified chitosan polymer and a nitric oxide dimer, wherein the nitric oxide dimer is covalently bound to the modified chitosan polymer, forming a diazenium diolate (NONOate) derivative of the modified chitosan polymer (col.

6, lines 21-31), which reasonably satisfies the instant claimed embodiment "c" of a beneficial recited in instant claim 1. Smith et al. disclose complexes of NO and polyamines such as spermine and spermadine (col. 3, lines 6-11). Claim 13 recites "diazenium diolates." Claim 27 recites "SDD," which overlaps with the teaching of Smith et al. of spermine NONOates (col. 3, lines 6-11). Although Smith et al. do teach chisoan polmye-dianzenium dilotate conjugates, Smith et al. do not teach applicant's elected embodiment "c" of Polyactive polymer-diazenium diolated conjugate.

Llanos et al. (US Patent Publication No. 2002/0094440 A1) is added to show the general knowledge regarding omplantable devices, including stents, and biocompatible coating compositions comprising Solef and rapamycin. Llanos et al. teach the instant claimed limitation "a." Specifically, Llanos et al. teach implantable medical devices, including stents, and biocompatible coating compositions for use on said implantanble medical devices, wherein said coatings comprise a film-forming polyfluoro copolymer comprising the polymerized residue of a first moiety selected from the group consisting of vinylidenefluoride (VDF) and tetrefluoroethylerne (TFE), and the polymerized residue of a second moiety other than said first moiety and which is copolymerized with said first moiety; the second moiety being capable of providing toughness or elastomeric properties to the polyfluoro copolymer (paras. 0010; 0015). Llanos et al. exemplify a coating composition comprising Solef, which is applicant's elected fluorinated polymer (page 5, Example 1; see also instant specification, page 1, para. 0015). Applicant's elected polyfluoro polymer species (i.e. Solef) reads on instant claims 1, 2, 3, 4, 5, and 6. Also, Llanos et al. also exemplify a coating comprising biologically active agents;

namely, a polymeric coating composition comprising poly (VDF/HFP) and rapamycin (page 5, Example 3). Claim 13 recites "wherein the biologically active agent is selected from polyarginine, ..., rapamycin, everolimus (40-O-(3-hydroxy)propyl-rapamycin, 40-O-[2-(2-hydroxy)ethoxy]ethyl-rapamycin, 40-O-tetrazole-rapamycin, and diazenium diolates," which overlaps with the biologically active agent taught by Llanos et al. (page 5, Example 3). However, Llanos et al. do not teach applicant's elected embodiment "b" (i.e. Polyactive) or embodiment c (i.e. Polyactive-diazenium diolate conjugate).

Hunter et al. (US Patent Application Pub. No. 2005/0147643 A1) teach Polyactive, applicant's elected beneficial polymer species i.e. instant claimed embodiment "b." See paras. 0010, 0015, 0019, and 0165. Hunter et al. teach compositions for delivery of selected drugs via medical implants or implantable medical devices, wherein the compositions may be coated onto the implant/implantable device (paras. 0010, 0019). Hunter et al. also compositions for delivering fibrosing agents, including chemotherapeutic agents (see reference claims 1482-1491).

Zhu et al. (US Patent 6,331,547) is added to show the general knowledge regarding polymeric pegylated SDZ-RAD conjugate; SDZ-RAD is a 40-O-(2-hydroxy) ethyl rapamycin analog (col, 2, line 65 to col. 4, line 10; see also reference claim 17).

Griffiths et al. (US Patent 7,011,812) is added to show the general knowledge regarding drug-polymer conjugates, PEG-drug conjugates, and drug-liposome conjugates (to col. col. 5, line 8 to col. 8, line 53, especially col. 5, lines 23-28). Griffiths et al. teach that linkage of a drug directly onto a polymer can result in a polymer-drug complex as a prodrug since one would expect that the drug will exerts its effect after

cleavage and the polymer-drug complex will coextensively have a lower toxicity profile than the free drug (col. 5, lines 38-43).

Based on the teaching of Smith et al. (US Patent 6,451,337) that there remains a great need to develop a low cost, readily biodegradable, biocompatible nitric oxide donor polymer composition comprising a nitric oxide dimer and a medically beneficial carrier molecule capable of improved site specific delivery and controlled release of nitric oxide (NO) to target tissues under physiological conditions, without the further side effects of the nitric oxide donor compounds (col. 3, lines 63 to col. 4, lines 3), someone of skill in the art would have been motivated to combine the teachings of the above cited references to create the instant claimed inventive concept.

Thus, someone of skill in the art at the time the instant invention was made would have found it obvious to create the instant claimed invention with reasonable predictability.

LACK OF WRITTEN DESCRIPTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claim 9 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim 9 is directed to encompass cellulosics compounds which only correspond in some undefined way to the

specifically instantly disclosed chemicals. None of the undisclosed cellulosics compounds meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed compounds, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only the disclosed chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Claim rejections – 35 USC 112 – Second Paragraph

The following is a quotation of the second paragraph of 35 USC 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 13, and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the term "poly(ethylene glycol)_(PEG)." This term renders the claimed subject matter indefinite because it is not clear what the term specifically means. For instance, the specific term "(PEG") could be considered to be an acronym for the term "poly(ethylene glycol)." Alternatively, the "poly(ethylene glycol)_(PEG)" could be construed to represent a complex molecule of comprising "poly(ethylene glycol" and "(PEG)."

It is suggested that this rejection could be overcome by amending the claim to delete the mark "_" between the term "poly(ethylene glycol)" and "(PEG)."

Dependent claims 2-11, 13, and 27 are rejected for the same reason as these claims fail to correct the deficiency of the claim from which they depend.

Claim 13 recites the terms "c-RGD" and "Rensten-NG," but fails to state the full meaning of the terms at the first occurrence the terms are recited in the claim. This limitation is vague and indefinite because it is not clear what these terms specifically mean. It is suggested that this specific rejection may be overcome by either replacing each term with the full name or, alternatively, amend the claim by inserting the full name in parenthesis at the first occurrence of each term in the claim.

Relevant Art of Record

The below cited art made of record and relied upon are considered pertinent to applicant's invention.

Garvey (US Patent 7,345,053 teaches nitrosated and/or nitrosylated rapamycin compounds and compositions comprising said compounds, wherein said compounds/compositions can be bound to a matrix (abstract; col. 9, lines 1-53; col. 37, line 56 to col. 38, line 56). Garvey teaches NONOates, including MAHMA/NO, PAPA/NO, spermine NONOate and, DEA/NO (col. 37, line 56 to col. 38, line 52), which overlap with applicant's elected beneficial polymer species (i.e. diazenium diolates). Garvey teaches that rapamycin compounds may be optionally nitrosated and/or nitrosylated can be incorporated into a natural or synthetic matrix which can then be applied with specificity to a biological site of interest (col. 46, line 38 to col. 47, line 16). Garvey teaches that all means of association, incorporation, attachment, and bonding of the rapamycin compound to the matrix are contemplated (col. 46, line 38 to col. 47, line 4).

Hoffman et al. (US 6,165,509) is added as an evidenciary reference to show the state of the art regarding pegylated drug complexed with bioadhesive polymer suitable for drug delivery polymeric, wherein said complexed drug is a hydrophobic compound (e.g. Taxol or paclitaxel). See col. 1, line 15 to col. 2, line 5).

Fuller (US Patent 6,416,834; already made of record) teach an adhesion-promoting additive composition for use in elastomers which are desirable for use in a wide variety of commerical products, including wire coatings (col. 1, lines 11-19). In one embodiment, the invention is directed to a composition for improving adhesion between an elastomer and a fluoropolymer comprising A) a first polymer comprising an uncured unsaturated polymeric adduct formed by reacting a polymer having unsaturation in the backbone of the polymer chain with an unsaturated dicarboxylic acid or dicarboxylic acid anhydride, wherein the acid or anhydride moieties comprise at least three weight percent of the adduct, and B) a compound selected the group consisting of polyamino primary amines, polyamino primary amine carbamates, and condensation products of polyamino primary amines with aldehydes(col. 1, lines 44-55). Fuller disclose non-eleastomeric fluoropolymer layer composed of non-elastomeric tetrafluoroethylene polymers, including, polytetrafluoroethylene, coplymers of tetrafluoroethylene and fluorohexapropylene, copolymers of tetrafluoroethylene and perfluror(alkyl vinly) ether and copolymers of tetrafluoroethylene and ethylene; polyvinylidene fluoride or copolymers of vinylidene fluoride with at least one monomer selected from the group consisting of fluorohexapropylene and tetrafluoroethylene may be utilized (col. 5, line 48 to col. 6, line 52).

Castro et al. (6,953,560; already made of record) teach a method for local delivery of drug involving coating a stent or graft with a polymeric material which, in turn, is impregnated with a drug or a combination of drugs; once the stent or graft is implanted within a cardiovascular system lumen, the drug(s) is released from the polymer for the treatment of the local tissue (col. 1, line 46 to col. 2, line 13). The implantable device includes a substrate e.g. a metal or polymeric stent or graft (col. 3, lines 27-30). At least a portion of the substrate is coated with a first layer that includes one or more drugs in a polymeric carrier; a barrier coating overlies the first layer (which reduces the rate of release of the drug from the polymer once the medical device is placed into a patient's body (col. 3, lines 30-37).

Fukushi (US Patent 6,759,129; already made of record) teach multi-layer article comprising a first polymer layer, a substrate, and a bonding layer on a surface of the first polymer layer which is in conact with the substrate, wherein the first polymer layer includes a fluoropolymer; the bonding layer includes a fluroelastomer comprising a monomer segment derived from an olefinic hydrocarbon (col, 1, lines 56-62). The fluoroelastomer can be a copolymer, which in addition to the olefinic hydrocarbon monomer, can be derived from fluorinated monomers e.g. Tetrafluoroethylene, vinylidene fluoride, hexafluoropropylene, fluorinated vinyl ethers or combination thereof (col. 2, lines 4-12; col. 6, lines 16-36). The substrate may include an inorganic substrate, such as a metal or an inorganic glass, or an organic substrate, such as a fluoropolymer or a non-fluorinated polymer (e.g. a polyamide, a polyolefin, a polyurethane, a polyester, a polyimide, a polystyrene, a polycarbonate, a polyketone, a

polyurea, a polyacryklate, and a polymethyl methacrykate, or a mixture thereof) (col. 6, line 56 to col 7, line 33). Useful polyols include, polypentyleneadipate, glycol, polytetramethylene ether glycol, polyethylene glycol, polycaprolactone diol, poly-1,2-butylene oxide glycol, and combinations thereof (col. 7, lines 46-49).

Davila et al. (US Patent 7,056,550; already made of record) teach a medical device for implantation into a treatment site of a living organism comprising a biocompatible vehicle affixed to at least a portion of the medical device, and at least one agent in therapeutic dosages incorporated into the biocompatible vehicle (col. 5, lines 24-53). Davila et al. exemplify a polyfluroro copolymer (Solef 21508) coating.

Fitzhugh et al. (US Patent 6,270,779) teach biocompatible metallic medical devices having silanized surfaces coupled to nucelophile residues that release sustained, therapeutic amounts of nitric oxide to specific sites within a mammalian body, wherein the biocompatible metallic medical device can be provided with anti-thrombogenic, lubricuous coatings that release sustained, therapeutic amounts of nitric oxide (abstract). NO's directly cytotoxic/cytostitc properties may sognificantly reduce vascular smooth muscle cell proliferation and help restenosis (col. 2, lines 1-5). Fitzhugh et al. propose metallic stents having drug releasing polymeric coatings (col. 6, lines 1-7). Fitzhugh et al. teach that polymeric stents present many unsolved challenges (col. 6, lines 7-13). Fitzhugh et al. disclose that arterial stents have been fabricated from a variety of compounds, including metals and biocompatible synthetic polymers (e.g. polypropylene, polyethylene, polyesters, polyethers, polyurethanes and polylactides). Fitzhugh et al. teach medical devices for delivering nitric oxide in

therapeutic concentrations for sustained periods of time comprising: metallic surfaces having nitric oxide releasably bound thereto through diazeniumdiolated nucleophiles coupled to silane intermediates, said silane intermediates being bound to said metallic surface (reference claim 12).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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2 July 2008

/Kevin E. Weddington/
Primary Examiner, Art Unit 1614

/C. R./
Examiner, Art Unit 1611